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(54) **Catheter for extracorporeal treatment.**

(57) A dual lumen catheter (100) is disclosed for providing extracorporeal treatment such as hemodialysis, which is percutaneously inserted for either short-term or long-term vascular access. The catheter includes a main body (101) having proximal and distal segments connected to a pair of clamping limbs (104,105) via a manifold (106). The distal segment (102) includes two tubular members (201,202) laterally attached to each other, one of which is thinner than the other and collapsible for inserting the catheter through a much smaller diameter peel-away sheath. Contrary to existing practices, the lengths of the arterial and venous tubular members are reversed such as to provide a longer negative pressure intake lumen. A hydrophilic slip coating (207) covers the distal segment (102) to further ease the insertion of the distal segment into the peel-away sheath. The cross-sectional area of the proximal segment (103) is generally elliptical shaped for providing a leak proof fit through the vascular access site. A ring-like grommet (116) moveable along the proximal segment anchors the catheter to the surrounding tissue. The lumens extending throughout the entire catheter are generally circular in nature and substantially equal in cross-sectional area to provide substantially equal flows of intake and return blood and to minimize clotting. The wall thickness of the negative pressure intake member (204) is approximately one and ~~a~~ half ~~to three~~ times as thick as that of the tin-walled positive pressure tubular wall (206) to maintain adequate flows of blood without collapsing or stretching.

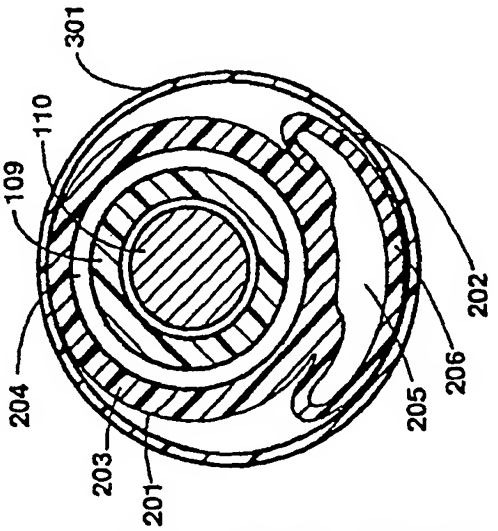

Fig. 3

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This invention relates to multilumen catheters.

One prior art hemodialysis plain tube catheter has provided good blood flow and can be left in place in the external or internal jugular vein for months or years. The flow characteristics are not ideal, but the catheter appears to maintain patency better than tapered tube catheters with side ports. The main problem with a plain tube catheter is its cross-sectional shape, which is similar to a double-barrelled shotgun with squared off ends, making it unsuitable for percutaneous insertion over a wire guide, or reinsertion into the same site. Peel-away sheath can be used for percutaneous insertion of catheters, but an 18 French sheath, required to accommodate large catheters, is judged to be undesirable.

Heretofore, it has always been considered necessary for positive pressure return lumens to extend beyond and thus downstream of the negative pressure intake lumens of a hemodialysis catheter. However, clots tend to adhere to the outside wall of the shorter intake lumen.

High efficiency dialysis requires the use of two large diameter lumens with an external cross-sectional dimension which is not too large for vascular access. One short-term catheter includes a simple double-D lumen configuration. The walls are thin, and the equal area lumens make full use of the available space, but in order to keep its shape during high flow rate dialysis, the catheter is made of relatively stiff material which is unsuitable for long-term placement. If silastic material is used for the intake lumen it would collapse under the influence of the strong negative intake pressure. Furthermore, the septum between the two lumens is pulled into the negative pressure lumen, thereby adversely changing the cross-sectional area in the two lumens as well as the blood flow rates therethrough.

Temporary or short-term catheters of the double-D configuration are universally used in large numbers but tend to get blocked. The use of stiff material causes the catheter to kink or buckle when bent more than 180°, resulting in obstruction, and cracking or splitting, and may be responsible for vein penetration injuries.

Silastic catheters with the double-barrelled shotgun configuration (two cylindrical lumens side by side) are remarkably resistant to kinking even when bent sharply through 180°. Cylindrical lumen achieve maximum flow for the smallest wall surface area and minimum clotting. They avoid the sharp corners in the wall of the double-D configuration.

The side-by-side open-ended design of the long-term catheter has much less tendency to block, but has not been used as a temporary catheter since it cannot easily be introduced percutaneously. The circular intake lumen of the long-term catheter is similarly recessed back from the distal end of the return lumen to minimize blood recirculation. A problem with this is that the wall of the extended positiv pressure return lumen provides a surface for clots to adhere. In an attempt to solve this blockage problem, the walls of the negative pressure intake lumen are provided with side ports. However, these side ports may actually encourage clotting.

The long term catheter typically employs a fixed-position dacron cuff which may not be conveniently positioned to stabilize the catheter. Removal of the catheter and release of the dacron cuff requires a new incision and dissection of the cuff by a surgeon. Dissecting the cuff from ingrown tissue invariably leads to bleeding, which may be hard to control.

According to the present invention there is provided a catheter as defined in claim 1.

When inserted in a vein, the collapsed lumen returns to its original shape.

The return lumen is thick enough to withstand the positive pressure of the returning blood without stretching.

The negative pressure intake lumen is longer than the positive pressure return lumen at the distal ends, and thus reduces the accumulation of blood clots and resulting blockage with only a minimal increase in blood recirculation between the two lumens.

To eliminate the seepage of blood between the tubular members where they penetrate the vein wall, the catheter has been segregated into distal and proximal segments. For percutaneous insertion, the distal segment advantageously includes the different thickness walls for collapsing the thin-walled positive pressure return lumen about the negative pressure intake lumen and inserting the collapsed distal segment through a smaller diameter introducer sheath. Extending proximally from the distal segment, the proximal segment has a cross-sectional shape of a generally elliptical character to form a leak proof fit when inserted into the vein wall. Furthermore, both of the segments are formed from a biocompatible material such as silastic for long-term use and have a predetermined durometer for pushing the catheter through the introducer sheath and blood vessel.

Brief description of the drawings

FIG.1 depicts a catheter;

FIG.2 depicts a cross-sectional view of the distal segment of the catheter of FIG.1 along the line 2-2;

FIG.3 depicts a cross-sectional view of the distal segment of the catheter of FIG.1 in a collapsed state and positioned in an introducer sheath; and

FIG.4 depicts a cross-sectional view of the proximal segment of the catheter of FIG.1 along the line 4-4.

Depicted in FIG.1 is a dual lumen catheter 100 for use in an extracorporeal treatment such as

hemodialysis and the like. This vascular access catheter is percutaneously inserted in a blood vessel, such as preferably the jugular or femoral vein, for either short-term or long-term hemodialysis treatment of the patient. The jugular access site is preferable to the subclavian vein because it is much less likely to cause subclavian vein thrombosis. Subclavian vein thrombosis is a serious long-term disability for a patient on dialysis if it is not diagnosed and successfully treated at an early stage, because it interferes with A-V fistula construction in the ipsilateral arm, leading to a permanently swollen congested arm as long as the fistula is functioning. Internal jugular vein thrombosis is probably not common after internal jugular cannulation, but it causes no disability even if it occurs and is not treated, except that the patient loses a potential access site.

The catheter basically comprises a dual lumen main body 101 attached to a single lumen, arterial clamping limb 104 and a single lumen, venous clamping limb 105 via interconnecting manifold 106. For connection to extracorporeal treatment equipment, two female Luer lock connectors 107 and 108 are connected in a well-known manner to arterial and venous clamping limbs 104 and 105, respectively. The main body of the catheter includes a distal segment 102 and a proximal segment 103 extending proximally therefrom and is comprised of a flexible biocompatible material such as 70 durometer silicon or silastic. Distal segment 102 includes a thick-walled, negative pressure, elongated tubular member 201 and a shorter, thin-walled, collapsible, positive pressure, elongated tubular member 202 attached laterally thereto. The catheter further includes lockable clamps 117 and 118 for clamping arterial and venous clamping limbs 104 and 105, respectively. One such clamp is the BETA-CAP clamp. Qosina slide clamps are also acceptable.

Catheter 100 also includes an anchoring grommet 116 having a ring-like collar 111 positioned around and slideably moveable along proximal segment 103. Flange 112 and 113 extend laterally from the collar and have respective apertures 114 and 115 formed therein to insert sutures therethrough. The grommet is positioned on the proximal segment where it crosses the supraclavicular fossa. Sutures placed through the apertures secure the catheter to the surrounding tissue. The shape of the grommet permits capture of the catheter without compressing it. The smooth rounded flanges allow the grommet to be pulled out with the catheter when it is removed. The anchoring sutures will tear out of the flanges and the only thing left inside the patient will be the sutures themselves.

The overall length of the main body of the catheter from the manifold to the distal tip thereof depends on the insertion site selected by th physician. When inserted in the right jugular vein, the main body of the catheter from manifold to tip is preferably 26cms in length with an 11cms distal segment. For the left jugular site, the main body of the catheter is approximately 30cms in length with the distal segment being 15cms. As suggested, the distal segment 102 includes a collapsible tubular member 202 for inserting the distal segment with stiffening cannula 109 inserted in tubular member 201 over wire guide 110 through a well-known smaller diameter peel-away introducer sheath (not shown). The introducer sheath should be no more than 10cm. in length. This will allow the distal segment to be inserted into the sheath with the distal tip protruding slightly beyond the distal end of the sheath before it is peeled away.

Member 202 is attached laterally to member 201 and collapsible thereon. Member 201 (FIG.2) includes first wall 203 surrounding first longitudinal passageway 204 included therein. This first longitudinal passageway is designated a negative pressure intake lumen for receiving blood from the vessel of a patient for hemodialysis treatment. By way of example, the thickness of first wall 203 is approximately 0.020" with the cross-sectional diameter of passageway 204 being approximately 0.080". The distal end of lumen 204 may be outwardly tapered to prevent clotting and the collection of blood clots thereon. The dimensions of member 201 and lumen 204 allow for blood flow rates of 350-400ml. per minute without collapsing.

Member 202 includes a second longitudinal passageway 205 with second wall 206 positioned thereabout. The thickness of wall 206 is approximately 0.010" with longitudinal passageway having a cross-sectional diameter of approximately 0.080", being approximately equal to that of passageway 204. In an uncollapsed state, the maximum cross-sectional dimension of distal segment is approximately 0.210" plus allowances for fabrication and slip coating 207, which will pass through an 18 French (0.236") aperture. Passageway 205 is designated the positive pressure return lumen for returning blood to the vessel of the patient. The cross-sectional areas of passageways 204 and 205 are substantially equal to provide approximately equal flow rates to and from the patient. The distal segment also includes slip coating 207 which acts as a lubricant to insert the distal segment through the introducer sheath. One such slip coating is a slippery-when-wet hydrophilic coating that is commercially available from Hydromer Inco., Whitehouse, New Jersey. The slip coating is applied to the outside surface of distal segment 102. This hydrophilic slip coating is wetted during the insertion procedure to provide a slippery surface for easier insertion through the peel-away introducer sheath. Furthermore, the presence of blood or other fluids in the introducer sheath further lubricates the collapsed distal segment as it is being inserted therethrough. This further eases the percutaneous insertion of the catheter when inserting a collapsed catheter having

an 18 French uncollapsed cross-sectional dimension through a 12 French introducer sheath. Another lubricious slip coating is Dow Corning medical-grade silicone fluid spray, applied by the physician just prior to percutaneous insertion of the catheter.

Experimentally, a 30cms thin-walled, positive pressure member of a 70 durometer silicon material catheter was able to tolerate a blood flow of 500mls per minute and a negative pressure of 300mm/Hg without collapsing when flows were reversed, and it was used as a negative pressure lumen. In clinical practice, the ability to reverse the flows is important if on occasion the thick-walled lumen fails to provide adequate out flow. The dialysis treatment community has been demanding these flow rates, but until now has not been provided with catheters to provide these flow rates. Experiments indicate that blood flow rates of 400mls per minute are attainable with arterial and venous pressure barely exceeding 200mms of mercury.

The cross-sectional shape of the passageways are also preferably circular to maintain maximum laminar fluid flow for a given wall surface area. The introduction of a smaller radius into the cross-sectional shape of the passageway typically provides opportunities for the blood flow to become turbulent and increases the risk of clotting.

A number of competing factors are involved with the dimensions associated with the wall thicknesses and lumen diameters. The tubular members must be thin and flexible enough for insertion into the vascular system without kinking or collapsing in operation. Wall 203 must be thick enough to withstand the negative pressures inwardly exerted thereon by modern hemodialysis machines without collapsing during intake of blood from the patient. Thinner, positive pressure lumen wall 206 must be thick enough to withstand the positive pressures outwardly exerted thereon without stretching. The diameter of the passageways should be as large as possible to provide adequate flow rates as demanded by hemodialysis. Lastly, the maximum cross-sectional dimension of the catheter must be minimal for percutaneous insertion into the blood vessel such as through a 12 French (0.158") peel-away introducer sheath. As a result, the thickness of wall 203 is preferably twice as thick as that of wall 206. Furthermore, the thickness of wall 203 may range from one and a half to three times as thick as that of positive pressure lumen wall 202.

This thin wall construction permits the collapse of member 202 about member 201 as depicted in FIG.3. In the collapsed state, the catheter typically having a maximum cross-sectional dimensi n of 18 French can be percutaneously inserted with stiffening cannula 109 ver wire guid 110 into a blood vessel through a much smaller 12 French diameter peel-away introducer sheath 301.

The cross-sectional shape 401 (FIG.4) of the proximal segment is formed to provide a tight fit between the main catheter body and the vascular access insertion site. Preferably, the cross-sectional shape is elliptical to prevent the seepage of blood from the vascular access site along the outside surface of the proximal segment of the main catheter body. Respective negative and positive pressure lumens 204 and 205 extend entirely through proximal segment 103.

To insert the dual lumen catheter using the well-known Seldinger technique, a wire guide 110 is inserted through an introducer needle into the accessed vein. The introducer needle is removed, and a 12 French sheath mounted on a dilator is directly inserted over the guidewire into the vein. Stiffening cannula 109 is inserted through the negative pressure lumen of the arterial clamping limb 104, proximal segment 103, and out the distal tip end of distal segment 102. The catheter and stiffening cannula are inserted over wire guide 110 and through the peel-away sheath with the thin-walled tubular member 202 collapsed. The peel-away sheath is removed after the distal segment is inserted through the sheath into the vein. A short distal portion of the elliptically shaped proximal segment 103 is then inserted through the venous access site into the vein, thereby establishing a relatively tight and leak-proof seal.

Grommet 116 is mounted onto the catheter by passing it over the distal tip, after the catheter has been pulled up through the subcutaneous tunnel and before the catheter is inserted through the sheath into the vein. Grommet 116 slides the distal segment and a length of proximal segment 103 and is placed strategically in the supraclavicular fossa and anchored to the subcutaneous tissue before the supraclavicular wound is closed. Final position of the grommet will vary in each patient according to how much length of the catheter is desired in the blood vessel.

To change the catheter, it will only be necessary to re-open the supraclavicular incision and remove the subcutaneous silk sutures which are anchoring the grommet in place. To remove the catheter without intending to replace it with another one in that same track, the catheter is subjected to a steady pull. This will tear the sutures out of the flanges of the grommet.

A number of alternative grommets may be slid over or attached to the proximal segment of the catheter for anchoring the catheter to surrounding tissue. The catheter may also include any number of other connectors or clamping devices for use with the arterial and venous clamping limbs. Furthermore, the shape of th lumens may be varied to an lliptical or even crescent shape; however, the radii of lumen shapes need to be maximized to prevent or minimize turbulent blood flow and the possibility of cl tting.

Claims

1. A catheter for extracorporeal treatment, said catheter comprising first (201) and second (202) elongated members, the first elongated member having a first longitudinal passageway (204) therein and a first wall (203) about said first passageway, said first wall having a first predetermined thickness; characterised in that the second elongated member is attached to and collapsible on said first member and has a second longitudinal passageway (205) therein and a second wall (206) having a second predetermined thickness about said second passageway, said first wall thickness being greater than said second wall thickness.

2. The catheter of claim 1, characterised in that said first wall thickness is at least one and a half times as thick as said second wall thickness.

3. The catheter of claim 1, characterised in that said first wall thickness is up to three times as thick as said second wall thickness.

4. The catheter of claim 1,2 or 3, characterised in that the first and second passageways are of generally circular cross section.

5. The catheter of claim 4, characterised in that the passageways are of approximately equal area.

6. The catheter of any one preceding claim, characterised in that the first passageway comprises a negative pressure intake lumen and the second passageway comprises a positive pressure return lumen, and in that said first and second members are respective first and second predetermined lengths, said first member being longer than said second member at distal ends thereof.

7. The catheter of any one preceding claim, further characterised by a slip coating about a distal end of said first and second members.

8. The catheter of any one preceding claim, characterised in that the said first and second members form part of a first elongated segment (102), and a second elongated segment (103) extending proximally from said first segment and having said first and second longitudinal passageways extending therein.

9. The catheter of claim 8, characterised in that said second segment has a first predetermined cross-sectional shape.

10. The catheter of claim 9, characterised in that said first predetermined shape is generally elliptical.

11. The catheter of claim 8,9 or 10, further characterised by a collar positionable about said second segment and having a flange securable to tissue.

12. The catheter of claim 8,9,10 or 11, characterised in that the distal end of said first passageway is tapered.

13. The catheter of any one of claims 8 to 12, characterised in that said first and second segments comprise a biocompatible material having a predetermined durometer.

14. A collapsible dual-lumen hemodialysis catheter for percutaneous insertion through a smaller diameter introducer sheath, comprising: an elongated distal segment having a negative pressure intake lumen and a positive pressure return lumen extending longitudinally therein, said lumens having substantially equivalent cross-sectional circular areas and first and second walls, said first wall positioned about said intake lumen and having a first predetermined thickness and a first predetermined length, said second wall positioned about said return lumen and having a second predetermined thickness and a second predetermined length, said first thickness being approximately twice as thick as said second thickness, said first wall being a predetermined distance longer than said second wall at a distal end of said distal segment, said distal segment in a collapsed state having said second wall and said return lumen being collapsed about said first wall and said intake lumen and having a maximum cross-sectional dimension less than said smaller diameter introducer sheath, said distal segment also having a slip coating thereon; an elongated proximal segment extending proximally from said distal segment and having a generally elliptical cross-sectional shape, said lumens extending longitudinally through said proximal segment; and a moveable collar positioned about said proximal segment and having a flange with a suture hold therein.

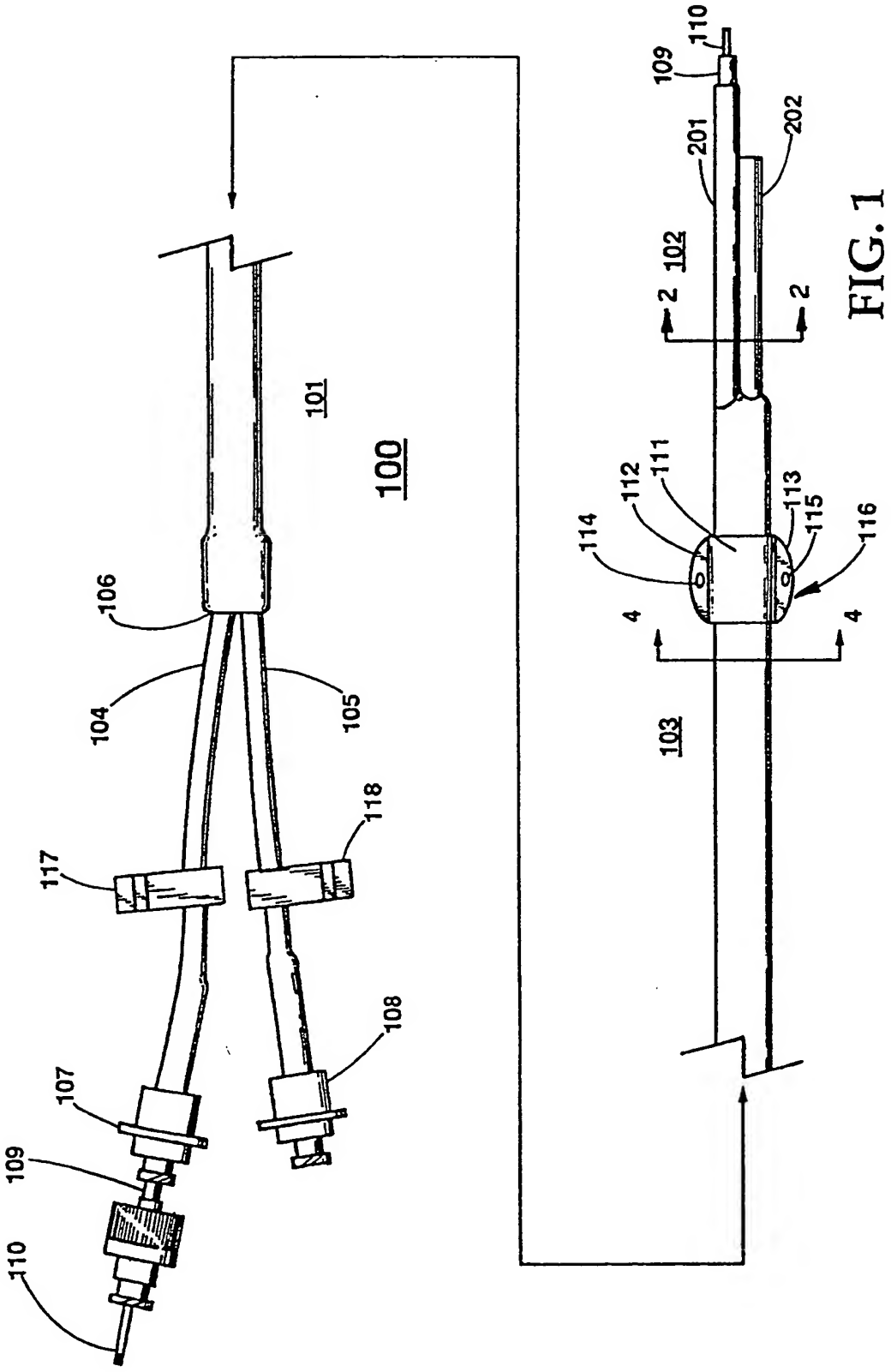
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FIG. 1

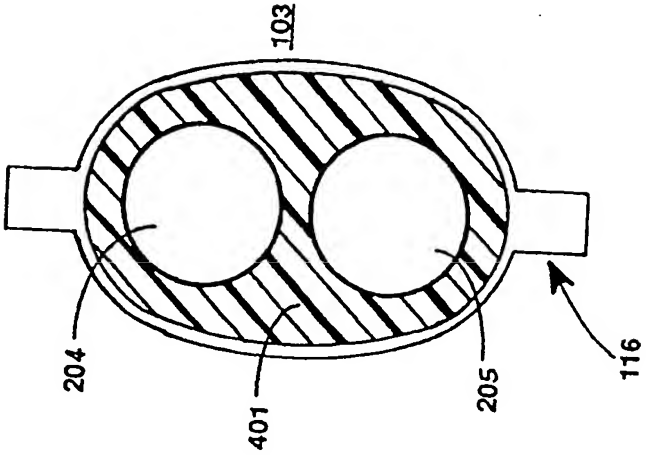

Fig. 4

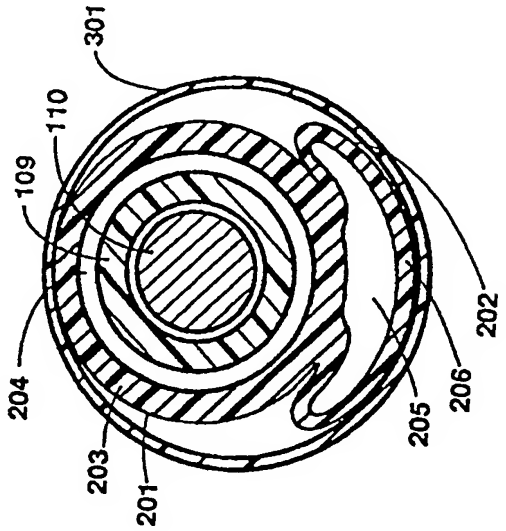

Fig. 3

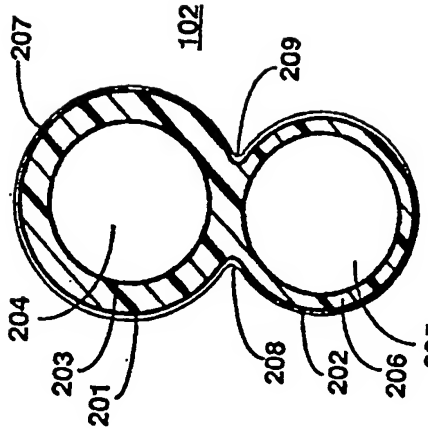

Fig. 2

European Patent Office

EUROPEAN SEARCH REPORT

Application Number EP 91 30 3368

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	WO-A-8 607 267 (GENUS) * Page 19, lines 3-28; figures 7,8 *	1-4	A 61 M 25/00
A	US-A-4 643 711 (BATES) * Description; figures *	1,6,8,9,10,11,14	
A	DE-A-2 912 852 (MATOUSCHEK) * Claim 1 *	7	
A	EP-A-0 093 887 (AIGNER) * Abstract; figure 1 *	1,8,9,12	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A 61 M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	03-07-1991	VANRUNXT J.M.A.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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